DEPARTMENT OF HEALTH AND HUMAN SERVICES

GS2004

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

February 8, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2005-07

Sjerp Ysselstein, President
Ysselstein Dairy, Inc.
1760 300th Street
Rock Valley, Iowa 51247-7547

Dear Mr. Ysselstein:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow owned by your firm. As a follow-up to USDA's finding, our investigator performed an inspection of your operation on October 25 & 28, 2004 and November 1, 2004. The inspection confirmed that you offered an animal for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act), and that you caused an animal drug to become adulterated within the meaning of section 501(a)(5) of the Act.

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. A dairy cow owned by your firm and culled for slaughter for human food was found to contain illegal levels of a drug residue by the United States Department of Agriculture (USDA) testing.

On September 10, 2004, USDA/FSIS collected a sample which tested positive for the presence of sulfamethazine residues at 3.19 parts per million (ppm) in the muscle tissue and 5.27 ppm in the liver tissue. The samples were collected from a culled dairy cow identified with a retain tag number [redacted] and USDA Sample Number 415018. Tolerance levels for residues of animal drugs in foods are found in Title 21, Code of Federal Regulations, Part 556 (21 CFR 556). The established tolerance for residues of sulfamethazine in cattle is 0.1 ppm (21 CFR 556.670). The presence of this drug, at a level above the tolerance, in edible tissue from the animal causes the food to be adulterated pursuant to Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that could allow medicated animals bearing potentially harmful drug residues to enter the food supply. For example, as noted on the form FDA-483 issued to you on November 1, 2004, you do not have an adequate

system to control the administration of drug treatments, and you fail to maintain treatment records. Foods from animals held under such conditions are adulterated pursuant to Section 402(a)(4) of the Act.

Sulfamethazine is not approved for use in dairy cows. However, the extra label use of approved veterinary or human drugs is allowed if the use complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 CFR Part 530. Our investigation found that your extra label use of sulfamethazine failed to comply with these requirements. For example, your use of sulfamethazine resulted in the presence of drug residue in edible tissue that might present a risk to public health, 21 CFR 530.11(c). In addition, it appears you have been administering sulfamethazine without the benefit of a valid veterinarian client-patient relationship, 21 CFR 530.10(a). Because your extra label use of sulfamethazine was not in compliance with 21 CFR 530, the drug was unsafe under Section 512(a) of the Act and your use caused it to be adulterated within the meaning of Section 501(a)(5) of the Act.

This is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction. You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

We note that this is not the first time an illegal residue has been found in a cow owned by you. On September 19, 2003 USDA/FSIS collected a sample which tested positive for the presence of sulfamethazine residues at 38.90 ppm in the liver, and 31.74 ppm in the muscle tissue from a culled dairy cow identified with a retain tag number [redacted] and USDA Sample Number 431907. This same liver sample tested positive for the presence of flunixin residue at 0.324 ppm. A tolerance is established for residues of sulfamethazine at 0.1 ppm in uncooked edible tissues of cattle (21 CFR 556.670). For flunixin the established tolerance for its use in cattle is 0.125 ppm in the liver.

We are aware that your have obtained a consulting veterinarian, [redacted], to assist you in addressing the issues identified during the inspection. We have received a memorandum, dated November 8, 2004, from [redacted] detailing his farm visit of November 3, 2004 including observations and recommendations made as well as actions taken. He also provided

us a memorandum, dated November 12, 2004, with details of his follow-up visit to Ysselstein Dairy.

You should notify this office in writing within fifteen (15) working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Joseph G. Kramer at the address indicated on the letterhead.

Sincerely,

C.R. Lambeth

for/ Ann M. Adams, Ph.D.
Acting District Director
Kansas City District